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L6: Entry 19 of 34

File: USPT

Apr 24, 2001

US-PAT-NO: 6221341

DOCUMENT-IDENTIFIER: US 6221341 B1

TITLE: Tooth whitening compositions

DATE-ISSUED: April 24, 2001

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Montgomery, R. Eric	Monterey	MA		

## ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
OraCeutical LLC	Monterey	MA			02

APPL-NO: 09/ 196403 [PALM]

DATE FILED: November 19, 1998

## PARENT-CASE:

This application claims the benefit of U.S. Provisional Application No. 60/066,187 filed Nov. 19, 1997.

INT-CL: [07] A61 K 7/16, A61 K 7/20

US-CL-ISSUED: 424/53; 424/49

US-CL-CURRENT: 424/53; 424/49

FIELD-OF-SEARCH: 424/53

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

Search Selected

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*Terminal  
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	PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
<input type="checkbox"/>	<u>2955905</u>	October 1960	Davies et al.	8/11
<input type="checkbox"/>	<u>3901819</u>	August 1975	Nakagawa et al.	252/186
<input type="checkbox"/>	<u>3956159</u>	May 1976	Jones	252/104
<input type="checkbox"/>	<u>4016090</u>	April 1977	Nakagawa et al.	252/102
<input type="checkbox"/>	<u>4610799</u>	September 1986	Wilsbere et al.	252/90
<input type="checkbox"/>	<u>4800038</u>	January 1989	Broze et al.	252/124.17
<input type="checkbox"/>	<u>4950424</u>	August 1990	van der Hoeven et al.	252/540
<input type="checkbox"/>	<u>5011622</u>	April 1991	Schepers	252/124.15
<input type="checkbox"/>	<u>5047168</u>	September 1991	Broze et al.	252/174.17
<input type="checkbox"/>	<u>5102574</u>	April 1992	Russell et al.	252/174.21
<input type="checkbox"/>	<u>5151212</u>	September 1992	Boll et al.	252/186.38
<input type="checkbox"/>	<u>5279816</u>	January 1994	Church et al.	424/53
<input type="checkbox"/>	<u>5290566</u>	March 1994	Schow et al.	424/49
<input type="checkbox"/>	<u>5302375</u>	April 1994	Viscio	424/53
<input type="checkbox"/>	<u>5447725</u>	September 1995	Damani et al.	424/435
<input type="checkbox"/>	<u>5503765</u>	April 1996	Schepers et al.	252/95
<input type="checkbox"/>	<u>5816802</u>	October 1998	Montgomery	433/80
<input type="checkbox"/>	<u>5885554</u>	March 1999	Michaels et al.	424/49
<input type="checkbox"/>	<u>5908614</u>	June 1999	Montgomery	427/53
<input type="checkbox"/>	<u>5922307</u>	July 1999	Montgomery	427/53
<input type="checkbox"/>	<u>5939080</u>	August 1999	Michaels et al.	424/401

## FOREIGN PATENT DOCUMENTS

FOREIGN-PAT-NO	PUBN-DATE	COUNTRY	US-CL
0545594 A1	June 1993	EP	
93/20167	October 1993	WO	
97/0777	March 1994	WO	
97/11676	April 1997	WO	
99/40870	August 1999	WO	

ART-UNIT: 164

PRIMARY-EXAMINER: Rose; Shep K.

ATTY-AGENT-FIRM: Banner &amp; Witcoff, Ltd.

## ABSTRACT:

Novel compositions and methods are disclosed for cosmetically treating teeth in a manner to increase brightness or shade of the teeth. The compositions include a low molecular weight compound having a high acetyl group functionality useful in the production of a peroxy acid which then acts as a whitening agent.

2 Claims, 0 Drawing figures

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## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Montgomery; R. Eric	Monterey	MA		

US-CL-CURRENT: 424/53; 424/49

## CLAIMS:

What is claimed is:

## 1. A method for whitening teeth comprising:

forming a composition having a pH in excess of about 5.2 by combining a hydrogen peroxide precursor in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the oral care composition, glyceryl triacetate in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the oral care composition, and water so as to generate peroxyacetic acid; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

## 2. A method for whitening teeth comprising:

providing separately glyceryl triacetate and a hydrogen peroxide releasing compound, both in an orally safe and sufficient amount for whitening teeth;

forming a composition having a pH in excess of about 5.2 including a mixture between the glyceryl triacetate and the hydrogen peroxide releasing compound with the glyceryl triacetate being in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the composition and with the hydrogen peroxide releasing compound being in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the composition; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

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TITLE: Tooth whitening compositions

Brief Summary Text (8):

Among the chemical strategies available for removing or destroying tooth stains, the most effective compositions contain an oxidizing agent, such as hydrogen peroxide, in order to attack the chromogen molecules in such a way as to render them colorless, water-soluble, or both. In one of the most popular approaches to whitening a patient's teeth, a dental professional will construct a custom made dental bleaching tray for the patient from an impression made of the patient's dentition and prescribe the use of an oxidizing gel to be dispensed into the bleaching tray and worn intermittently for a period of from about 2 weeks to about 6 months, depending upon the severity of tooth staining. These oxidizing compositions, usually packaged in small plastic syringes or tubes, are dispensed directly by the patient into the custom-made tooth-bleaching tray, held in place in the mouth for contact times of greater than about 60 minutes, and sometimes as long as 8 to 12 hours. The slow rate of bleaching is in large part the consequence of the very nature of formulations that are developed to maintain stability of the oxidizing composition. The most commonly used oxidative compositions contain the hydrogen peroxide precursor carbamide peroxide which is mixed with an anhydrous or low-water content, hygroscopic viscous carrier containing glycerin and/or propylene glycol and/or polyethylene glycol. When contacted by water, carbamide peroxide dissociates into urea and hydrogen peroxide. Associated with the slow rate of bleaching in the hygroscopic carrier, the currently available tooth-bleaching compositions cause tooth sensitization in over 50% of patients. Tooth sensitivity is believed to result from the movement of fluid through the dentinal tubules, which is sensed by nerve endings in the tooth. The carriers for the carbamide peroxide enhance this movement. In fact, it has been determined that glycerin, propylene glycol and polyethylene glycol can each give rise to varying amounts of tooth sensitivity following exposure of the teeth to heat, cold, overly sweet substances, and other causative agents.

Brief Summary Text (12):

Of the many peroxides available to the formulator of tooth whitening compositions, hydrogen peroxide (and its adducts or association complexes, such as carbamide peroxide and sodium percarbonate) has been used almost exclusively. The chemistry of hydrogen peroxide is well known, although the specific nature of its interactions with tooth chromogens is poorly understood. It is believed that hydrogen peroxide destroys tooth chromogens in a similar fashion to that observed in the destruction of laundry stains, that is, by oxidizing unsaturated carbon-carbon, carbon-oxygen, and carbon-nitrogen bonds found in the stain molecules. A related class of compound, the peroxyacids, has been used in laundry detergents to effectively whiten clothes, due primarily to their stability in solution and their specific binding abilities to certain types of stain molecules. A number of stable, solid peroxyacids have been used, including diperoxydodecanoic acid and the magnesium salt of monoperoxyphthalic acid. Other peroxyacids, such as peroxyacetic acid, are available as solutions containing an equilibrium distribution of acetic acid, hydrogen peroxide, peroxyacetic acid and water. Alternatively, a peroxide donor such as sodium perborate or sodium percarbonate is formulated into a dry laundry detergent, together with a peroxyacid precursor. Upon contact with the wash water, the peroxide donor releases hydrogen peroxide into the wash solution, which then reacts with the peroxyacid precursor to form the actual peroxyacid. Examples of peroxyacids created in situ include peroxyacetic acid (from hydrogen peroxide and tetraacetylenediamine) and peroxy-nonanoic acid (from hydrogen peroxide and

nonanoyloxybenzene sulfonate).

Brief Summary Text (17):

The methods of the present invention employ compositions including at least one orally acceptable acyl group source or precursor and at least one orally acceptable peroxide source or precursor. The acyl group source and the peroxide precursor, upon contact with an aqueous solution, generate a peroxyacid. The acyl group source and the peroxide precursor may be dispersed within an anhydrous carrier.

Brief Summary Text (20):

According to one embodiment of the present invention, the composition includes at least two components: one component including a source of peroxide (such as hydrogen peroxide), and a second component including a source of acetyl groups. The two components may be mixed together prior to application of the resulting mixture to the tooth surface. Alternatively, each component may be sequentially applied directly to the tooth surface. It should be noted that either of the components may be applied first before the application of the remaining component.

Brief Summary Text (24):

The principles of the present invention may be applied with particular advantage to obtain compositions and methods for the whitening or stain removal of teeth. The present invention, in one embodiment, is directed to a composition that whitens the color of teeth when applied to a stained tooth surface. The composition may be provided as a multi-component formulation including a peroxide source and a source of acetyl or functionally similar groups, which when combined produces an active ingredient useful in teeth whitening, such as a peroxyacid. According to one embodiment, the peroxide source is hydrogen peroxide or a hydrogen peroxide precursor and the source of acetyl or functionally similar groups is a C.sub.1 -C.sub.5 molecule having between 1 to 5 labile C.sub.1 -C.sub.5 acyl containing groups.

Brief Summary Text (25):

Alternatively, in order to prevent premature reaction of the hydrogen peroxide or its precursor with the source of acetyl groups, an anhydrous formulation containing both the source of acetyl groups and hydrogen peroxide or its precursor is provided. The hydrogen peroxide or its precursor, and the the source of acetyl groups, upon placement against the stained tooth surface in the oral cavity, are activated by the aqueous content of the saliva to generate a peroxacid, such as peroxyacetic acid.

Brief Summary Text (26):

Alternatively, a composition may be manufactured having each of the hydrogen peroxide or its precursor and the source of acetyl groups as a separate and distinct component. According to this aspect of the invention, one component containing the source of acetyl groups may be applied to a stained tooth surface followed immediately thereafter by application onto the same tooth surface of a second component containing hydrogen peroxide or a hydrogen peroxide precursor. The sequence of application of such components may also be reversed depending upon the desired application. Such a sequential application would provide for the production of peroxyacetic acid in situ and is advantageously beneficial to accessing chromogens in tooth structures.

Brief Summary Text (28):

The hydrogen peroxide precursor for use in connection with the present invention is preferably selected from the group consisting of carbamide peroxide, sodium percarbonate, sodium perborate, calcium peroxide, magnesium peroxide, sodium peroxide, and the anhydrous poly(vinyl pyrrolidone)/hydrogen peroxide complexes. It is contemplated that any compound which, when in contact with water, is capable of generating, converting to, or otherwise becoming hydrogen peroxide or peroxide anion, will have utility in the formulation of the present inventive compositions. For instance, it is possible to utilize other alkali metal percarbonates (such as potassium percarbonate), as well as enzymatic sources of hydrogen peroxide, such as glucose oxidase in combination with beta-D-glucose. Additional useful peroxide precursors will become apparent to those skilled in the art based upon the present disclosure.

Brief Summary Text (29):

The peroxide precursor is present in the compositions of the present invention as they are applied directly to the tooth surface in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight. Higher levels of hydrogen peroxide may be used in conjunction with a supervised dental whitening procedure in which the soft tissue (i.e., the gingival and other mucosal surfaces) are physically isolated from the teeth being whitened. Hydrogen peroxide concentrations up to about 3 percent are acceptable for short-term (less than 60 minutes) incidental contact with soft tissue.

Brief Summary Text (30):

Compositions that utilize hydrogen peroxide itself, rather than a precursor, should be prepared as two or more components, keeping the source of acetyl groups in one component and hydrogen peroxide in the second component as an aqueous solution containing both hydrogen peroxide and the source of acetyl groups will quickly form a peroxyacid.

Brief Summary Text (32):

According to a specific preferred embodiment of the present invention, the source of labile acetyl groups is glyceryl triacetate, glyceryl diacetate or glyceryl acetate. The source of labile acetyl groups is present in the compositions of the present invention in an amount sufficiently high to allow for the rapid generation of peroxyacid, i.e. in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the composition.

Brief Summary Text (33):

Glyceryl triacetate (CAS No. 102-76-1) has a molecular weight of about 218.20 and is available as a colorless, oily liquid with a slight fatty odor. It is soluble in water up to a concentration of approximately 7.1% by weight in water and is generally prepared by the acetylation of glycerol. Glyceryl triacetate has an extremely low order of toxicity and is listed as GRAS (Generally Regarded as Safe as a direct food additive) in the Code of Federal Regulations, Title 21, Part 184.1901. It is therefore ideally suited for use in oral care products.

Brief Summary Text (34):

The use of glyceryl triacetate is advantageous due to its highly labile acetyl functionalities (which is important to obtaining effective tooth whitening levels of peroxyacetic acid in the presence of hydrogen peroxide), its low level of oral toxicity, and its unexpected ability to penetrate into intact tooth enamel upon contact to a tooth surface. Additionally, glyceryl triacetate degrades, in the presence of peroxide, into acetic acid (after first converting to peroxyacetic acid), water, and other degradation products that are toxicologically acceptable. While not wishing to be bound to any particular theory, the tightly packed crystal structure of tooth enamel and, to a lesser degree, dentin renders the tooth relatively impermeable to high molecular weight compounds such as proteins and polysaccharides. In addition, both the hydroxyapatite crystals and their supporting collagen matrix act as permselective barriers to diffusion of many types of molecules. In particular, highly polar or strongly charged ionic species (such as amines and glycols) do not penetrate the tooth structure to the same degree as relatively non-polar or uncharged species. The source of labile acetyl groups advantageously has a sufficiently low molecular weight which allows it to penetrate pores within teeth. Suitable compounds will have molecule weights below 1000, preferably below 500 and most preferably in a range similar to glyceryl triacetate, i.e. between 300 and 100.

Brief Summary Text (36):

According to an additional embodiment, the pH of the tooth whitening composition may be controlled during use as the generation of peroxyacid from hydrogen peroxide and glyceryl triacetate is pH-dependent.

Brief Summary Text (37):

The composition of the present invention may be applied to the stained tooth surface as liquids, gels, pastes, sprays, or as solid delivery systems (for instance, chewing gum or dental floss). The composition may be applied to the tooth surface in the form of a single component anhydrous formulation, a multi-component anhydrous or

aqueous formulation mixed prior to application, or a multi-component anhydrous or aqueous formulation mixed directly on the tooth surface by sequential application of two or more components.

Brief Summary Text (39):

In one embodiment, the single component composition remains relatively anhydrous to prevent premature generation of peroxyacetic acid from the interaction of hydrogen peroxide with glyceryl triacetate in aqueous solution. As the composition is anhydrous, it is necessary to utilize a hydrogen peroxide precursor, such as those provided above, which is not only soluble or dispersible, but stable in the carrier.

Brief Summary Text (42):

The compositions of the present invention may also contain a buffer to provide a specific pH for optimal penetration of the composition into tooth enamel or to provide for optimal generation of peroxyacetic acid from the hydrogen peroxide precursor and glyceryl triacetate. Suitable buffers include sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium phosphate di- and tri-basic, potassium phosphate di- and tri-basic, sodium tripolyphosphate, tris(hydroxymethyl)aminomethane, triethanolamine, polyethylenimine, and other alkaline buffers. Within a particular formulation, an alkaline buffer may also serve the purpose of neutralizing carboxylic acid side chains in thickening polymers such as polyacrylic acid and poly(methyl vinyl ether-co-maleic anhydride). Acid buffers, such as citric acid, phosphoric acid, and others may also be used alone or in conjunction with an alkaline buffer to obtain the desirable pH and to provide buffering capacity. The level of buffer, when present, is from about 0.5 percent by weight to about 3.0 percent by weight of the composition. It is to be understood that additional useful buffers will become apparent to those skilled in the art based upon the disclosure herein.

Brief Summary Text (43):

The formation of peroxyacetic acid from hydrogen peroxide and glyceryl triacetate has been determined to occur most readily at pH levels in excess of about 5.2. However, peroxyacetic acid is only stable at an acid pH if formulated fully within a composition. Therefore, it is seen to be preferred to provide compositions that generate peroxyacetic acid in situ at a pH more suited to producing it quickly for use in the oral cavity. In this manner, tooth stains can be removed at a much more rapid rate through the use of the present compositions.

Brief Summary Text (44):

Compositions of the present invention may optionally contain one or more chelating agents for the purpose of scavenging metal ions in the composition and during use of the composition. Metals, such as iron, manganese, and copper, and their oxides are known in the art to cause the degradation of hydrogen peroxide through Fenton-type reactions. This particular degradation mechanism is undesirable in that the hydroxyl free radical (OH $\cdot$ ) is created and is not as effective as the perhydroxyl anion (HOO $^{--}$ ) in attacking chromogens. Therefore, it is desirable to encourage the dissociation of hydrogen peroxide into perhydroxyl anions, rather than hydroxyl radicals, in order to maximize the effectiveness of the inventive compositions. It may also be desirable to provide conditions in the inventive compositions which are conducive to the formation of peroxyacetic acid (CH<sub>3</sub>COOOH) and its dissociated species, the peroxyacetate anion (CH<sub>3</sub>COO $^{--}$ ). In a similar fashion as above, the peroxyacetate anion is much more effective as a bleaching or whitening agent than free radical species, such as the peroxyacetyl radical (CH<sub>3</sub>COO $\cdot$ ), which form in the presence of metal ions and their oxides.

Detailed Description Text (13):

Two solutions, A and B, were prepared from a stock solution of 10% hydrogen peroxide adjusted to a pH of 5.20 with 10% NaOH. Solution A was the same as the stock solution of 10% hydrogen peroxide, while Solution B contained 6% w/w of glyceryl triacetate (FCC grade, Spectrum Chemical, Gardena, Calif.). Initial color readings were recorded for each bovine enamel sample and the samples were marked either "A" or "B". The samples were immersed in their corresponding solutions and allowed to whiten for periods of 30 minutes. After each 30-minute period, the samples were removed and placed in distilled water for 60 seconds. The samples were then removed,

dried, and color readings were taken. Four treatments were performed on one day, followed by a distilled water storage overnight, after which another four treatments were performed, utilizing fresh solutions. Following the eight treatments, the samples were placed in yet another fresh solution and allowed to remain immersed for another 24 hours to achieve their maximum attainable whiteness. The results of the eight 30 minute treatments, along with the data for both the distilled water overnight storage period and the 24 hour immersion, are shown in Table 1 below.

Detailed Description Text (14):

It is clear from the comparative .DELTA.E values above that the stained enamel specimen labeled as sample "B" experienced a much more rapid whitening effect than sample "A", especially following the first few 30-minute treatments. It should be noted that sample B, after four treatments in Solution B containing 10% hydrogen peroxide and 6% glyceryl triacetate, experienced a large decrease in its b value (down to 5.84 from 10.68) during the 12 hour distilled water immersion between treatment days. Such an effect was not observed for sample A which was immersed in the 10% hydrogen peroxide solution alone.

Detailed Description Text (19):

As is evident from the data above, the composition containing the peroxyacid precursor having three labile acetyl functionalities and a low molecular weight, i.e. Sample B containing glyceryl triacetate, generated the most whitening capability. In contrast, the sample containing the high molecular weight species tetraacetythylenediamine delivered significantly less whitening capability, while the samples containing the high molecular weight species acetylsalicylic acid and poly(vinyl pyrrolidone-co-vinyl acetate) delivered dramatically less whitening capability.

Detailed Description Text (21):

Another test was done to determine the effect of pH on the oral composition of the present invention at a given concentration of hydrogen peroxide. Two solutions, C and D, were prepared from a stock solution of 10% hydrogen peroxide. Solution C was adjusted to a pH of 5.20 with 10% NaOK, while solution D was adjusted to a pH of 7.80 with 10% NaOH. Just prior to immersion of the stained bovine enamel specimens into solution, 6% w/w of glyceryl triacetate (FCC grade, Spectrum Chemical, Gardena, Calif.) was added to each solution. Initial color readings were recorded as above and the samples were marked either "C" or "D". The samples were immersed in their corresponding solutions and allowed to whiten for periods of 30 minutes. After each 30-minute period, the samples were removed and placed in distilled water for 60 seconds. The samples were then removed, dried, and color readings were taken as above. Three treatments were performed in sequence. Following the three treatments, the samples were placed in yet another fresh solution and allowed to remain immersed for another 24 hours to achieve their maximum attainable whiteness. The results of the eight 30 minute treatments, along with the data for both the distilled water overnight storage period and the 24 hour immersion, are shown in Table 2 below.

Detailed Description Text (24):

A commercially available product used in an office setting by dentists utilizes 35% hydrogen peroxide and corresponds to a composition described in U.S. Pat. No. 5,032,178. A mixture to be applied to a stained tooth surface was prepared according to the manufacturer's instructions and used to determine its ability to remove tooth stain as above (a total of only two applications was done). The results are shown in Table 3 below.

Detailed Description Text (25):

From Table 3, it can be seen that even though the commercial product utilizes 30-35% hydrogen peroxide as an oxidizer, it did not perform as well as solution "D", which contains only 10% hydrogen peroxide and glyceryl triacetate, after two treatments.

Detailed Description Text (28):

The above composition was manufactured under a vacuum of 26-26" Hg in a Ross double planetary mixer (Charles Ross & Son, Hauppauge, N.Y.). All product contact parts in the mixer were either KYNAR-coated metal or plastic in order to prevent leaching of contaminant metals (such as iron, copper, and manganese) into the composition during manufacture. KYNAR (a DuPont trademark) is a fluoropolymer coating used to, among



other purposes, prevent corrosion of steel or metal parts in the presence of aggressive chemicals. These same product contact parts were also passivated by contacting them with a solution of 10 w/w percent hydrogen peroxide and subsequently rinsed with distilled water just prior to use.

Detailed Description Text (29):

The above composition was prepared by placing the polyethylene glycol into the mixing chamber, adding the sodium saccharin and glyceryl triacetate, and allowing to mix under vacuum at high speed until a clear solution was obtained. The polyvinylpyrrolidone was then added and mixed under vacuum at high speed until homogeneously dispersed. The fumed silica was then added, with slow mixing, to the above phase in the mixing chamber. The addition of the fumed silica resulted in a high degree of thickening of the total mixture. Finally, after the complete homogenization of the above dispersion (the thickened carrier matrix), the sodium percarbonate powder was added and dispersed thoroughly, again under vacuum and high speed mixing. Finally, the flavor was added and completely blended into the mixture. The resulting bleaching composition was a slightly off-white gel. The composition was transferred to polypropylene syringes for storage and testing.

Detailed Description Text (33):

After manufacture, each of the above compositions was placed in a separate chamber of a dual-chamber syringe, the type having a plunger mechanism whereby externally applied pressure to the plunger forces each of the two components through a mixing chamber (known in the art as a static mixer) attached to the end of the dual-chambered syringe. A further description of this method of combining and mixing two incompatible components for the purpose of bleaching teeth can be found in the copending U.S. patent application Ser. No. 09/054,156 filed Apr. 2, 1998 hereby incorporated by reference in its entirety. Just prior to use, the two separate components are forced by the externally applied pressure into one end of the static mixer, travel through baffles in the static mixer which force the two components to blend together, and finally emerge from the opposite end of the static mixer as a single, homogeneous mixture. The resulting mixture thus contains both the hydrogen peroxide precursor and glyceryl triacetate, and alternatively, water in a sufficient amount to allow the production of peroxyacetic acid for whitening the teeth.

Detailed Description Text (37):

A further embodiment of the present invention provides for the combination of a hydrogen peroxide precursor and glyceryl triacetate in situ. In this mode of applying the inventive compositions, a first composition containing one of either the hydrogen peroxide element or the glyceryl triacetate element is placed directly onto the tooth surface to be whitened. A period of time may be allowed for the first element to penetrate into the tooth structure. Then, a second composition containing the remaining inventive composition element is placed directly onto the same tooth surface that has already been contacted with the first composition. In this manner, both the hydrogen peroxide precursor element and the glyceryl triacetate element are present on the stained tooth surface simultaneously. Peroxyacetic acid is thereby generated on and within the stained tooth providing a method of applying the inventive compositions (and whitening teeth in general) having certain advantages over other approaches.

Detailed Description Text (38):

Since peroxyacids (and peroxides in general) are highly reactive species, an in situ method of applying and subsequently generating oxidizing agents on and within a stained tooth surface is advantageous. By generating the peroxyacid (in this invention, peroxyacetic acid) on and within the tooth (thus in intimate contact with the stain-causing molecules themselves), superior tooth whitening results may be obtained. Although not wishing to be bound by any particular theory, it is believed that deeper penetration into the tooth structure by a first element (one of either a hydrogen peroxide precursor composition or a glyceryl triacetate composition) prior to contact with the second element will generate peroxyacetic acid (upon placement of the second remaining element) at the same site reached by the first element. In this manner, the depth at which tooth whitening occurs by the inventive compositions may be controlled. The in situ method described above has an additional advantage, in that the amount of peroxyacetic acid can be limited to that amount formed within the tooth structure itself (i.e. only where both of the required elements are

Detailed Description Text (39):

Detailed Description Text (41):

Detailed Description Text (44) :

Detailed Description Text (46):

Detailed Description Paragraph Table (2):

Detailed Description Paragraph Table (3):

Detailed Description Paragraph Table (7):

Detailed Description Paragraph Table (8):

Detailed Description Paragraph Table (C)															
TABLE 5 Percent (w/w)		A		B		C		Ingredient		1 2 1 2 1 2		Propylene glycol		42.56 45.00	
Polyethylene glycol 400		70.00		73.40		Polyethylene glycol 600		23.00		33.90		Glycerin		5.00 5.00 5.00 5.00	
Distilled water		2.67		69.24		82.80		Sodium saccharin		0.80		0.80		Potassium acesulfame 1.00	
Dequest 2010		0.10		0.40		Sodium stannate		0.02		Flavor		0.80		1.00 1.20	
Carbopol 974P		2.00		2.00		5.00		5.00		Hydroxypropylcellulose		10.00		10.00	
Fumed silica		12.00		12.00		Poly(vinylpyrrolidone-co vinyl acetate)		1.00		Sodium hydroxide monohydrate		2.67		Ammonium hydroxide 29% 3.20	
Carbamide peroxide		12.00		Sodium percarbonate powder		8.00		Hydrogen peroxide		35%		17.14		Glyceryl triacetate 2.50	
2.00		1.60		TOTAL		100.00		100.00		100.00		100.00		100.00	

100.00

Detailed Description Paragraph Table (9):

Ingredient	Percent (w/w)	Polyethylene glycol 400	34.76	Polyethylene glycol 3350	1.00
Water	1.80	<u>Glyceryl triacetate</u>	2.00	<u>Sodium percarbonate</u>	5.00
50.00		Hydrated silica	1.60	Sodium lauryl sulfate	0.60
0.60		Sodium fluoride	0.24	Sodium methyl cocoyl taurate	1.20
		Sodium saccharin	1.20	Flavor	1.20
				TOTAL	100.00

## CLAIMS:

## 1. A method for whitening teeth comprising:

forming a composition having a pH in excess of about 5.2 by combining a hydrogen peroxide precursor in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the oral care composition, glyceryl triacetate in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the oral care composition, and water so as to generate peroxyacetic acid; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

## 2. A method for whitening teeth comprising:

providing separately glyceryl triacetate and a hydrogen peroxide releasing compound, both in an orally safe and sufficient amount for whitening teeth;

forming a composition having a pH in excess of about 5.2 including a mixture between the glyceryl triacetate and the hydrogen peroxide releasing compound with the glyceryl triacetate being in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the composition and with the hydrogen peroxide releasing compound being in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the composition; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

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L11: Entry 1 of 2

File: USPT

Apr 24, 2001

US-PAT-NO: 6221341

DOCUMENT-IDENTIFIER: US 6221341 B1

TITLE: Tooth whitening compositions

DATE-ISSUED: April 24, 2001

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Montgomery, R. Eric	Monterey	MA		

US-CL-CURRENT: 424/53; 424/49

## CLAIMS:

What is claimed is:

## 1. A method for whitening teeth comprising:

forming a composition having a pH in excess of about 5.2 by combining a hydrogen peroxide precursor in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the oral care composition, glyceryl triacetate in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the oral care composition, and water so as to generate peroxyacetic acid; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

## 2. A method for whitening teeth comprising:

providing separately glyceryl triacetate and a hydrogen peroxide releasing compound, both in an orally safe and sufficient amount for whitening teeth;

forming a composition having a pH in excess of about 5.2 including a mixture between the glyceryl triacetate and the hydrogen peroxide releasing compound with the glyceryl triacetate being in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the composition and with the hydrogen peroxide releasing compound being in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the composition; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

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File: USPT

Apr 24, 2001

US-PAT-NO: 6221341

DOCUMENT-IDENTIFIER: US 6221341 B1

TITLE: Tooth whitening compositions

DATE-ISSUED: April 24, 2001

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Montgomery, R. Eric	Monterey	MA		

US-CL-CURRENT: 424/53; 424/49

## CLAIMS:

What is claimed is:

## 1. A method for whitening teeth comprising:

forming a composition having a pH in excess of about 5.2 by combining a hydrogen peroxide precursor in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the oral care composition, glyceryl triacetate in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the oral care composition, and water so as to generate peroxyacetic acid; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

## 2. A method for whitening teeth comprising:

providing separately glyceryl triacetate and a hydrogen peroxide releasing compound, both in an orally safe and sufficient amount for whitening teeth;

forming a composition having a pH in excess of about 5.2 including a mixture between the glyceryl triacetate and the hydrogen peroxide releasing compound with the glyceryl triacetate being in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the composition and with the hydrogen peroxide releasing compound being in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the composition; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.